DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

g1340d

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

19900 MacArthur Blvd., Ste 300
Irvine, California 92612-2445
Telephone (949) 798-7600

June 4, 2001

Naishu Wang, M.D., Ph.D
President
Alfa Scientific Designs, Inc.
12330 Stowe Drive
Poway, CA 92064

PINL-03-1

Dear Dr. Wang:

The Food and Drug Administration (FDA) conducted an inspection of your firm's medical device manufacturing facility at 12330 Stowe Drive, Poway, California from April 17 to April 25, 2001. The inspection covered your in vitro diagnostic kits. Profile classes SIP and DKA were covered.

At the end of the inspection, the FDA investigator left a list of inspectional observations (Form FDA 483 dated April 25, 2001) at your firm. We have received your firm's written responses, dated May 2, May 11, and May 25, 2001 to the Form FDA 483. Copies of these responses and the Form FDA 483 are enclosed.

While this inspection found deficiencies of your quality system that would warrant a warning letter if not corrected, your written response has satisfied us that you either have taken or are taking appropriate corrective actions. At this time, FDA does not intend to take further action based on these inspectional findings. The agency is relying on your commitment regarding corrective actions and, should we later observe that the deviations from the quality system regulation have not been remedied, future regulatory action (e.g., seizure, injunction and/or civil penalties) may be taken without further notice.

Based upon corrective action, the deficiencies noted during FDA's inspection will not affect applicable pending premarket submissions or export certificates for devices manufactured at your facility that were specificially inspected. This information is available to Federal agencies when they consider awarding contracts.

There may be other devices and operations of your firm for which the conclusions from this inspection are not applicable. The agency may separately inspect your firm's facilities to address the quality system regulation in these areas.

Your firm has an ongoing responsibility to conduct internal self-audits to assure you are continuing to maintain conformance with the quality system regulation.

For further information, please contact FDA Senior Compliance Officer, Dannie E. Rowland at (949) 798-7649.

Sincerely,

Alonza E. Cruse
District Director

Enclosures

Cc: State Department of Public Health
Envirnomental Health Services
Attn: Chief, Food and Drug Branch
601 North 7th Street, MS-357
Sacramento, CA 94234-7320